Carolinas Medical Center
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1433 '00 JAN -3 A11:20

Department of Obstetrics and Gynecology

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

RE: Docket #97N-484S, Suitability Determination for Donors of Human cellular Tissue-based Products

To Whom It May Concern,

This letter is in reference to the recent FDA Federal Register report proposing rules regarding donor egg in vitro fertilization. The proposal suggests a requirement to test an egg donor before the donor egg IVF cycle, freeze the resultant embryos and quarantine them until 6 months later when the egg donor is retested for infectious diseases. This requirement is not based on scientific fact and interferes with the practice of medicine. There is no evidence that HIV or any infectious diseases are passed through in vitro fertilization. In addition, this would significantly increase cost, decrease success rates and will result in the unnecessary deaths of embryos and potential human lives. I strongly object to these rules from scientific, legal, infectious disease, practical, monetary and medical practice aspects. As a provider of fertility services it will significantly impair my ability to help patients while providing no benefit. Please reconsider these proposed rules and support only those proposals based on scientific fact.

Sincerely,

Michelle L. Matthews, MD
Assistant Director, Reproductive Endocrinology
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